REMARKS

Claims 250-251, 253-279, 281-288, and 290-304 are pending in the present application, claims 301-304 having been added and claims 252, 280, and 289 having been cancelled without prejudice or disclaimer herein. The Decision on Appeal and cited references have been carefully considered and the points made there are believed to have been addressed by the amendments presented above. Favorable reconsideration is respectfully requested.

Claims 250, 256, 257, 270, 272, 274-276, 281, 285, 287, and 282-292 were rejected under 35 U.S.C. §103 as being unpatentable over Applicant's Disclosed Prior Art ("ADPA"), Stanton (U.S. Patent Application No. 2002/0039990), Rivette (U.S. Patent No. 5,991,751) and D'Ambra (U.S. Patent No. 6,458,958). Claims 251, 252, 254, 258, 282[1], 286, 288 and 289 were rejected under 35 U.S.C. §103 as being unpatentable over ADPA, Stanton, Rivette, D'Ambro, and Colombo (U.S. Patent No. 5,678,234). Claims 253, 255, 259, 262, 263, 265, 267, 279, 271, 273, 279 and 290 were rejected under 35 U.S.C. §103 as being unpatentable over ADPA, Stanton, Rivette, D'Ambro, Colombo, and Risen (U.S. Patent No. 6,018,714). Claims 260, 261, 264, 266, 268, 277 278, 280, 283, 284, and 291 were rejected under 35 U.S.C. §103 as being unpatentable over ADPA, Stanton, Rivette, D'Ambro, and Risen. Claims 299 and 300 were rejected under 35 U.S.C. §103 as being unpatentable over ADPA, Stanton,

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[1] Applicant requests that the oversights raised in Footnote 2, page 4, of the Decision on Appeal be corrected in the next Office Action, if the application is not passed to issue.

Rivette, D'Ambro, and Jacob (U.S. Patent No. 3,885,566). These rejections are respectfully traversed for the following reasons.

Claim 250 recites a method of commercializing at least one previously unreported proprietary method of using a product of manufacture or device, wherein the proprietary method of using the product or device is established according to the steps comprising accessing one or more data sources, wherein at least one data source stores adverse event data associated with the product or device, analyzing and comparing the stored adverse event data, with at least one previously-known adverse event associated with the product or device, identifying at least one previously unreported essential adverse event associated with the product or device from the adverse event data, wherein an essential adverse event is one regulated by a regulatory agency requiring disclosure of the event in a package insert or data sheet accompanying the product or device, and wherein an essential adverse event is unreported if it has not been reported in any known accessible database, and then responsive to identifying of the previously unreported essential adverse event, identifying at least one previously unreported method of use for the product or device associated with said identified essential adverse event, documenting inventorship of the at least one previously unreported method of use for the product or device, and creating a database of proprietary essential adverse event information, wherein the database stores at least one record related to at least one of: a patent, patent application, patent publication, or data contained in at least one patent, patent application or patent publication, wherein said at least one patent, patent application, patent publication, or

data contained in at least one patent, patent application or patent publication, discloses and relates to at least one of the at least one previously unreported method of use and the at least one essential adverse event, and wherein the at least one previously unreported proprietary method of using a product or device consists of a use selected from the group consisting of a restricted use of said product or device, providing warning(s) about the essential adverse event, providing instruction(s) for avoiding an essential adverse event, and any combination thereof, and commercializing the at least one previously unreported proprietary method of using a product or device, the commercializing comprising exclusively disclosing the at least one previously unreported proprietary method of use and the associated at least one previously unreported essential adverse event information, which information, once identified, must then accompany the product or device, wherein commercializing means creating profit from the exclusive disclosure. This is not taught, disclosed or made obvious by the prior art of record.

The cited prior art does not disclose identifying at least one previously unreported essential adverse event associated with the product or device from the adverse event data***, wherein an essential adverse event is one regulated by a regulatory agency requiring disclosure of the event in a package insert or data sheet accompanying the product or device, and wherein an essential adverse event is unreported if it has not been reported in any known accessible database***.

The cited prior art also does not disclose creating a database of proprietary essential adverse event information, wherein the database stores at least

one record related to at least one of: a patent, patent application, patent publication, or data contained in at least one patent, patent application or patent publication, wherein ***said at least one patent, patent application, patent publication, or data contained in at least one patent, patent application or patent publication, discloses and relates to at least one of the at least one previously unreported method of use and the at least one essential adverse event***.

The prior art also does not disclose ***commercializing the at least one previously unreported proprietary method of using a product or device, the commercializing comprising exclusively disclosing the at least one previously unreported proprietary method of use and the associated at least one previously unreported essential adverse event information, which information, once identified, must then accompany the product or device, wherein commercializing means creating profit from the exclusive disclosure.*** This is supported in that in the related application that issued as U.S. Patent No. 7,653,639, the feature of exclusive disclosure of the newly-identified proprietary essential adverse event information which once identified, must then accompany the product or device. Applicant respectfully submits that this feature is also not found in the cited art of the present application.

For at least these reasons, Applicant respectfully submits that claim 250 is patentable over the prior art of record whether taken alone or in combination as proposed in the Office Action. Claims 303-304 are believed to be patentable at least for the reasons discussed above with respect to claim 250. Additionally, claims 251, 253-

279, 281-288, and 290-301 are believed to be patentable in and of themselves, and for the reasons discussed above with respect to claim 250.

For example, claim 251 recites that the method further comprises determining value of commercializing the at least one use determined from the at least one identified essential adverse event, wherein the value depends on a potential value of making a generic product or device into a proprietary product or device, or preventing a proprietary product or device from becoming a generic product or device. In the Decision on Appeal, the Board were not convinced that the specification's definition of determining the value of commercialization such that the prior art did not teach or suggest determining the value of commercializing at least one use for a product or device. Applicant has amended claim 251 to recite that the value depends on a potential value of making a generic product or device into a proprietary product or device, or preventing a proprietary product or device from becoming a generic product or device. This is not taught in the cited prior art.

Claim 302 recites a method of commercializing at least one previously unreported proprietary method of using a product of manufacture or device, comprising accessing one or more data sources, wherein at least one data source stores adverse event data associated with the product or device, analyzing and comparing the stored adverse event data, with at least one previously-known adverse event associated with the product or device, identifying at least one previously unreported essential adverse event associated with the product or device from the adverse event data, wherein an essential adverse event is one regulated by a regulatory agency requiring disclosure of

the event in a package insert or data sheet accompanying the product or device, and wherein an essential adverse event is unreported if it has not been reported in any known accessible database, and then responsive to identifying of the previously unreported essential adverse event, identifying at least one previously unreported method of use for the product or device associated with said identified essential adverse event, documenting inventorship of the at least one previously unreported method of use for the product or device, and creating a database of proprietary essential adverse event information, wherein the database comprises at least one of: a patent, patent application, patent publication, or data contained in at least one patent, patent application or patent publication, said at least one patent, patent application, patent publication, or data contained in at least one patent, patent application or patent publication, which discloses and relates to the at least one previously unreported method of use, and wherein the at least one previously unreported proprietary method of use consists of a use selected from the group consisting of a restricted use of said product or device, providing warning(s) about the essential adverse event, providing instruction(s) for avoiding an essential adverse event, and any combination thereof, wherein the at least one previously unreported proprietary method of use is not a pharmacogenomic technique for screening, and commercializing the at least one previously unreported proprietary method of use, the commercializing comprising exclusively disclosing the at least one previously unreported proprietary method of use and the associated at least one previously unreported essential adverse event information, which information, once identified, must then accompany the product or

device, wherein commercializing means creating profit from the exclusive disclosure. The Board suggested that the arguments concerning the relevance of Stanton because the invention was not intended to encompass pharmacogenomic techniques for screening, was not persuasive because the claims were not so limited. Claim 302 has been added and recites that "the at least one previously unreported proprietary method of use is not a pharmacogenomic technique for screening…."

In view of the above amendment and remarks, Applicant respectfully requests reconsideration and withdrawal of the outstanding rejections of record. Applicant submits that the application is in condition for allowance and early notice to this effect is most earnestly solicited.

If the Examiner has any questions, he is invited to contact the undersigned at 202-628-5197.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By /Ronni S. Jillions/
Ronni S. Jillions
Registration No. 31,979

RSJ:me
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
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